

FORM PTO-1449B

INFORMATION DISCLOSURE  
CITATIONAttorney Docket:  
4439-4026Serial No.:  
10/511,693Applicant:  
Masayuki AMAGAI, et al.Filing Date:  
October 14, 2004Group Art Unit:  
1632

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
AS	1.	Amagai M, Hashimoto T, Shimizu N, and Nishikawa T: "Absorption of pathogenic autoantibodies by the extracellular domain of pemphigus vulgaris antigen (Dsg3) produced by baculovirus," <i>J Clin Invest</i> , 94:59-67, July 1994.
	2.	Amagai M, Klaus-Kovtun V, and Stanley JR: "Autoantibodies against a novel epithelial cadherin in pemphigus vulgaris, a disease of cell adhesion," <i>Cell</i> , 67:869-877, November 29, 1991.
	3.	Amagai M, Koch PJ, Nishikawa T, and Stanley JR: "Pemphigus vulgaris antigen (Desmoglein 3) is localized in the lower epidermis, the site of blister formation in patients," <i>J Invest Dermatol</i> , 106:351-355, 1996.
	4.	Amagai M, Tsunoda K, Suzuki H, Nishifuji K, Koyasu S, and Nishikawa T NishikawaT: "Use of autoantigen-knockout mice in developing an active autoimmune disease model for pemphigus," <i>J Clin Invest</i> , 105:625-631, 2000.
	5.	Chen M, O'Toole EA, Muellenhoff M, Medina E, Kasahara N, and Woodley DT WoodleyDT: "Development and characterization of a recombinant truncated type VIII collagen "minigene". Implication for gene therapy of dystrophic epidermolysis bullosa," <i>J Biol Chem</i> , 275(32):24429-24435, August 11, 2000.
	6.	Choate KA, Medalie DA, Morgan JR, and Khavari PA: "Corrective gene transfer in the human skin disorder lamellar ichthyosis," <i>Nat Med</i> , 2(11):1263-1267, November 1996.
	7.	Christensen R, Jensen UB, and Jensen TG: "Cutaneous gene therapy-an update," <i>Histochem Cell Biol</i> , 115:73-82, November 28, 2000.
	8.	Dai Y, Schwarz EM, Gu D, Zhang W-W, Sarvetnick N, and Verma IM: Cellular and humoral immune responses to adenoviral vectors containing factor IX gene: "Tolerization of factor IX and vector antigens allows for long-term expression," <i>Proc Natl Acad Sci</i> , 92:1401-1405, February 1995.
	9.	Datta SK, and Kalled SL: "CD40-CD40 ligand interaction in autoimmune disease," <i>Arthritis Rheum</i> , 40(10):1735-1745, October 1997.
	10.	Dellambra E, Vailly J, Pellegrini G, Bondanza S, Golisano O, Macchia C, Zambruno G, Meneguzzi G, and De Luca M: "Corrective transduction of human epidermal stem cells in laminin-5-dependent junctional epidermolysis bullosa," <i>Hum Gene Ther</i> , 9:1359-1370, June 10, 1998.
	11.	Freiberg RA, Choate KA, Deng H, Alperin ES, Shapiro LJ, and Khavari PA: "A model of corrective gene transfer in X-linked ichthyosis," <i>Hum Mol Genet</i> , 6(6):927-933, 1997.
✓	12.	Greenhalgh DA, Rothnagel JA, and Roop DR: "Epidermis: An attractive target tissue for gene therapy," <i>J Invest Dermatol</i> , 103:63S-69S, 1994.
AS	13.	Hengge U, Chan EF, Foster RA, Walker PS, and Vogel JC: "Cytokine gene expression in epidermis with biological effects following injection of naked DNA," <i>Nat Genet</i> , 10:161-166, June 1995.

Examiner Signature	/Anoop Singh/	Date Considered	01/06/2007
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AS	14.	Hengge UR, Walker PS, and Vogel JC: "Expression of naked DNA in human, pig, and mouse skin," <i>J Clin Invest</i> , 97(12):2911-6, June 1996.
	15.	Ilan Y, Prakash R, Davidson A, Jona V, Droguette G, Horwitz MS, Chowdhury NR, and Chowdhury JR: "Oral tolerization to adenoviral antigens permits long-term gene expression using recombinant adenoviral vectors," <i>J Clin Invest</i> , 99(5):1098-1106, March 1997.
	16.	Jensen TG, Jensen UB, Jensen PK, Ibsen HH, Brandrup F, Ballabio A, and Bolund L: "Correction of steroid sulfatase deficiency by gene transfer into basal cells of tissue-cultured epidermis from patients with recessive X-linked ichthyosis," <i>Exp Cell Res</i> , 209:392-397, March 1993.
	17.	Katsumi A, Emi N, Abe A, Hasegawa Y, Ito M, and Saito H: "Humoral and cellular immunity to an encoded protein induced by direct DNA injection," <i>Hum Gene Ther</i> , 5:1335-1339, November 1994.
	18.	Kay MA, Holterman AX, Meuse L, Allen Gown A, Ochs HD, Linsley PS, and Wilson CB: "Long-term hepatic adenovirus-mediated gene expression in mice following CTLA4lg administration," <i>Nat Genet</i> , 11:191-197, October 1995.
	19.	Khavari PA: "Gene therapy for genetic skin disease," <i>J Invest Dermatol</i> , 110(4):462-467, April, 1998.
	20.	Khavari PA: "Genetic correction of inherited epidermal disorders," <i>Hum Gene Ther</i> , 11:2277-2282, November 1, 2000.
	21.	Koch PJ, Mahoney MG, Ishikawa H, Pulkkinen L, Uitto J, Shultz L, Murphy GF, Whitaker-Menezes D, and Stanley JR: "Targeted disruption of the pemphigus vulgaris antigen (desmoglein 3) gene in mice causes loss of keratinocyte cell adhesion with a phenotype similar to pemphigus vulgaris," <i>J Cell Biol</i> , 137(5):1091-1102, June 2, 1997.
	22.	Larregina AT, and Falo LD: "Generating and regulating immune responses through cutaneous gene delivery," <i>Hum Gene Ther</i> , 11:2301-2305, November 1, 2000.
	23.	Morral N, O'Neal W, Zhou H, Langston C, and Beaudet A: "Immune responses to reporter proteins and high viral dose limit duration of expression with adenoviral vectors: comparison of E2a wild type and E2a deleted vectors," <i>Hum Gene Ther</i> , 8:1275-1286, July 1, 1997.
	24.	Ohshima M, Amagai M, Tsunoda K, Ota T, Koyasu S, Hata J, Umezawa A, and Nishikawa T: "Immunologic and histopathologic characterization of active disease mouse model for pemphigus vulgaris," <i>J Invest Dermatol</i> , 118:199-204, 2002.
	25.	Seitz CS, Giudice GI, Balding SD, Marinkovich MP, and Khavari PA: "BP180 gene delivery in junctional epidermolysis bullosa," <i>Gene Ther</i> , 6:42-47, 1999.
AS	26.	Stein CS, Martins I, and Davidson BL: "Long-term reversal of hypercholesterolemia in low density lipoprotein receptor (LDLR)-deficient mice by adenovirus-mediated LDLR gene transfer combined with CD <sub>154</sub> blockade," <i>J Gene Med</i> , 2:41-51, November 18, 1999.

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AS	27.	Tripathy SK, Black HB, Goldwasser E, and Leiden JM: "Immune responses to transgene-encoded proteins limit the stability of gene expression after injection of replication-defective adenovirus vectors," <i>Nat Med</i> , 2(5):545-550, May 1996.
	28.	Uitto J, and Pulkkinen L: "The genodermatoses: candidate disease for gene therapy," <i>Hum Gene Ther</i> , 11:2267-2275, November 1, 2000.
	29.	Vailly J, Gagnoux-Palacios L, Dell'Ambra E, Romero C, Pinola M, Zambruno G, De Luca M, Ortonne J-P, and Meneguzzi G: "Corrective gene transfer of keratinocytes from patients with junctional epidermolysis bullosa restores assembly of hemidesmosomes in reconstructed epithelia," <i>Gene Ther</i> , 1322-1332, 1998.
	30.	Vogel JC: "Keratinocyte gene therapy," <i>Arch Dermatol</i> , 129:1478-1483, November 1993.
	31.	Vogel JC: "Nonviral skin gene therapy," <i>Hum Gene Ther</i> , 11:2253-2259, November 1, 2000.
	32.	Yamada A, and Sayegh MH: "The CD154-CD40 costimulatory pathway in transplantation," <i>Transplantation</i> , 73(1):S36-S39, January 15, 2002.
	33.	Yang Y, Su Q, Grewal IS, Schilz R, Flavell RA, and Wilson JM, "Transient subversion of CD40 ligand function diminishes immune responses to adenovirus vectors in mouse liver and lung tissues," <i>J Virol</i> , 70(9): 6370-6377, September 1996.
	34.	Yao SN, Farjo A, Roessler BJ, Davidson BL, and Kurachi K, "Adenovirus-mediated transfer of human factor IX gene in immunodeficient and normal mice: Evidence for Prolonged Stability and Activity of the Transgene in Liver," <i>Viral Immunol</i> , 9(3):141-153, November 3, 1996.
	35.	Zeng L, Sarasin A, and Mezzina M: "Retrovirus-mediated DNA repair gene transfer into xeroderma pigmentosum cells," <i>Cell Biol Toxicol</i> , 14:105-110, 1998.
AS	36.	Spirito F, Meneguzzi G, Danos O, and Mezzina M: "Cutaneous gene transfer and therapy: the present and the future," <i>J Gene Med</i> , 3:21-31, December 22, 2000.

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